IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

TC HEARTLAND LLC, *Plaintiff and Counterclaim Defendant,* v. SUSAN S. SCHIFFMAN, *Defendant and Counterclaim Plaintiff.*	Civil Action No. 1:23-CV-00665

PLAINTIFF TC HEARTLAND LLC'S BRIEF IN SUPPORT OF MOTION FOR LEAVE TO FILE AN AMENDED COMPLAINT

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INTRODUCTION

Plaintiff TC Heartland LLC ("Heartland") respectfully moves the Court for leave to file an Amended Complaint based on information obtained in discovery. Based on this new information, Heartland seeks to add additional factual allegations supporting its current claims. The additional factual allegations show Schiffman's intentional misconduct in attempting to mask her defamatory and disparaging statements concerning Splenda products in the guise of science. Schiffman's fearmongering remarks on Splenda, sucralose, and sucralose-6-acetate ("S6A") are based on misleading, false, and unsupported claims. She selectively published and manipulated data and the designs of her research to achieve her desired end goal—harming Splenda products. Of course, Heartland can combat scientific flaws committed by Schiffman through the scientific process, but Heartland turns to the courts to rectify the damages caused by the fraudulent and misleading acts that Schiffman has perpetuated and that she has cloaked in a veneer of science to shield herself from criticism.

FACTUAL BACKGROUND

Heartland manufacturers Splenda—the number one recommended sweetener in America. Compl. ¶¶13, 15. Splenda is a sucralose based sweetener, which is an approved food product that passed a rigorous review. Countercl. ¶45. As an approved general-purpose sweetener, the sucralose used in Splenda is regularly tested for any impurities and remains a healthy alternative to sugar. Compl. ¶¶15, 35. In May 2023, Defendant Susan Schiffman ("Schiffman") published an article purporting to study S6A and sucralose (the "Article"). *Id.* ¶¶21–22. Based on this article, Schiffman embarked on a press tour targeting

Splenda. Compl. ¶30. She claimed that Splenda contained S6A, that S6A is genotoxic, and that her new work "*establishes*" that S6A has various adverse health effects. *Id.* But Schiffman never studied Splenda for her Article. Compl. ¶29. Heartland thus brought claims against Schiffman for defamation, trade libel, and violations of the North Carolina Unfair and Deceptive Trade Practices Act ("UDTPA").

In response, Schiffman filed a motion to dismiss Heartland's claims, arguing that Schiffman's statements were based on legitimate and protected scientific research. *See* Dkt. 16. The Court dismissed Heartland's claims "to the limited extent that they are based on alleged false statements about the results of Dr. Schiffman's research on sucralose and S6A and her resulting opinions based on that research." Dkt. 35 at 7. The Court noted that Heartland did not currently make any "allegations tending to support a plausible inference that Dr. Schiffman's research was based on fraudulent data or otherwise that her conclusions were a result of quackery." *Id.* at 2. Discovery commenced after the Court's ruling and is still underway. But documents produced by Schiffman and third parties have already shown Schiffman's statements are based on data manipulated to show the results that she wanted in her Article. These data manipulations are not innocent. They broke protocol for establishing a valid test in order to untruthfully create the result that Schiffman wanted. Troublingly, discovery has also uncovered that Schiffman chose *not* to publish other data in her possession showing that S6A is not genotoxic. Once again, this omission is not innocent. The omitted data is the exact same type of test she ran to reach her conclusion that S6A was genotoxic. The difference is the omitted data was run under the actual scientific protocols and produced the exact opposite result broadcast by Schiffman.

Instead, Schiffman selectively published test results that supported her preferred conclusion—a target that she could aim at Splenda.

QUESTIONS PRESENTED

Whether this Court should grant Heartland leave to amend its complaint under Rule 15's liberal standard to reflect (1) the evidence to date, including evidence that the Court commented was missing in her motion to dismiss order but that could not have been known to Heartland before discovery, and (2) corresponding allegations showing Schiffman selectively published data that supported that S6A is genotoxic, manipulated her research to achieve her desired conclusion, and misrepresented the conclusions in her Article.

LEGAL STANDARD

Under Rule 15(a), Courts are to grant leave to file an amended pleading "freely" "when justice so requires." Fed. R. Civ. P. 15(a)(2). The Supreme Court has reinforced that "this mandate is to be heeded." *Foman v. Davis*, 371 U.S. 178, 182 (1962). Although granting leave to amend is within a court's discretion, courts apply the mandate of Rule 15 liberally. *See, e.g.*, *Dominion Healthcare Servs., Inc. v. Value Options, Inc.*, 2009 WL 580326, at *4 (M.D.N.C. Mar. 5, 2009). In considering motions for leave to amend, courts consider five factors: (1) undue delay, (2) bad faith or dilatory motive by the movant, (3) "repeated failure to cure deficiencies by amendments previously,"[1] (4) "undue prejudice to the opposing party," (5) futility of amendment. *Foman*, 371 U.S. at 182.

[1] Heartland has not amended previously, and so Heartland has not had "repeated failure to cure deficiencies by amendments previously allowed." *Pickens v. Shanahan*, 2016 WL 9077908, at *2 (M.D.N.C. Nov. 15, 2016), *report and recommendation adopted*, 2016 WL 9053306 (M.D.N.C. Dec. 28, 2016).

ARGUMENT

The Court should grant leave to amend because each of the *Foman* factors weigh in favor of leave to amend.

I. Heartland's Amendment Is Timely.

Heartland has timely made its motion for leave to amend. During the Rule 26(f) conference, the parties agreed that Heartland could seek leave to amend its complaint by July 17, 2025. Dkt. 39 at 2. The Court approved the Rule 26(f) Report, including this deadline. Dkt. 41. The Parties subsequently consented to an extension of this deadline, and the Court allowed Heartland to seek leave through July 24, 2025. *See* Dkt. 48.

Heartland filed this Motion for leave within the Court-ordered schedule and is thus presumptively timely. *See Raleigh Flex Owner I, LLC v. Marketsmart Interactive, Inc*, 2010 WL 3211064, at *4 (M.D.N.C. Aug. 11, 2010) (rejecting argument of undue delay where the party sought leave to amend the complaint "within the time allotted by the Scheduling Order endorsed by all parties and adopted by the Court"); *PNY Techs., Inc. v. SanDisk Corp.*, 2014 WL 294855, at *4 (N.D. Cal. Jan. 27, 2014) (noting that moving for leave to amend within the stipulated deadline, even "on the last day," "strongly shows that [the party] did not unduly delay"). Indeed, Heartland brings this motion only after recently receiving discovery from Schiffman and third parties. Moreover, in the interest of bringing the motion by the Court-ordered deadline, Heartland filed the motion even though discovery is still ongoing. Waiting "until after the plaintiff attempts to conduct some discovery" before adding allegations is not an "improper course of action; to the contrary, one might well construe such an approach as reflecting responsible litigation practice."

Raleigh Flex, 2010 WL 3211064, at *4. Even if Heartland delayed (which it plainly did not), "[d]elay alone is an insufficient reason to deny leave to amend." *See Edwards v. City of Goldsboro*, 178 F.3d 231, 242 (4th Cir. 1999).

II. Heartland's Amendment Is Made in Good Faith.

Heartland moves in good faith to amend its complaint to better reflect the evidence to date. Under the liberal standard of Rule 15, good faith may be presumed in the absence of "any *explicit* showing of bad faith." *Dominion Healthcare Servs.*, 2009 WL 580326, at *4 (emphasis added). There is *no* explicit—let alone any implicit—evidence of bad faith. *See Jett v. Coleman*, 2024 WL 4942267, at *3 (E.D.N.C. Oct. 22, 2024), *report and recommendation adopted*, 2024 WL 4941308 (E.D.N.C. Dec. 2, 2024) (finding "no bad faith on the part of Plaintiffs in seeking to cure the deficiencies that led to the prior dismissal" of the claims). Heartland simply seeks to ensure the complaint reflects the factual record developed to date. *See, e.g.*, *In re Intuitive Surgical Sec. Litig.*, 2017 WL 363269, at *2 (N.D. Cal. Jan. 25, 2017) (finding no "bad faith when the result of an amendment may actually be beneficial to clarifying the allegations at issue").

III. Heartland's Amendment Is Not Unduly Prejudicial.

Heartland's proposed amendment is not prejudicial, let alone unduly so. Heartland filed this motion by the deadline the parties agreed to, which "alone makes it difficult for Defendant to establish prejudice." *Finishmaster, Inc. v. Booth*, 2017 WL 10925131, at *2 (M.D.N.C. Jan. 5, 2017). Moreover, discovery is still on-going. To date, no depositions have been conducted. *Cf. Raleigh Flex*, 2010 WL 3211064, at *5 (granting leave to amend where "both sides still need to take depositions and it appears that few, if any, depositions

have occurred"). Indeed, roughly four months remain in discovery, which closes on November 20, 2025. *See* Dkt. 39 at 2. And when "the motion to amend the pleadings came with four months remaining for discovery and within the time period for making a motion to amend," courts have held that defendants have "a heavy burden of showing prejudice." *PNY Techs.*, 2014 WL 294855, at *4.

Heartland's Amended Complaint adds additional factual allegations based on the same underlying course of conduct by Schiffman. Heartland adds no new causes of action; the additional factual allegations support Heartland's existing claims of defamation, trade libel, and violation of the North Carolina UDTPA. But even when a proposed amendment raises "a new legal theory" "not already considered by the opposing party," undue prejudice arises only "where the amendment is offered shortly before or during trial." *Finishmaster, Inc.*, 2017 WL 10925131, at *2 (granting leave to amend to add additional party and claims months before trial). No trial date has been set. The absence of any prejudice is a "strong indication that leave to amend should be allowed." *Dominion Healthcare Servs.*, 2009 WL 580326, at *3.

IV. Heartland's Amended Complaint Is Not Futile.

Lastly, Heartland's Amended Complaint is not futile. Denying leave to amend based on futility is proper only when "the proposed amendment is clearly insufficient or frivolous *on its face*." *Johnson v. Oroweat Foods Co.*, 785 F.2d 503, 510 (4th Cir. 1986) (emphasis added). "While leave to amend may be futile when an amended complaint could not survive a Rule 12(b)(6) motion, it does not follow that every motion seeking amendment should be decided . . . as a motion under Rule 12(b)(6)." *Earthkind, LLC v. Lebermuth Co.*

Inc., 2020 WL 8771419, at *2 (W.D.N.C. Dec. 1, 2020) (citation omitted); *see also Walintukan v. SBE Ent. Grp., LLC*, 2017 WL 635278, at *2 (N.D. Cal. Feb. 15, 2017) ("[I]f the underlying facts or circumstances relied upon by a plaintiff *may* be a proper subject of relief, he ought to be afforded an opportunity to test his claim on the merits." (emphasis added) (citation omitted)).

Heartland's Amended Complaint is far from frivolous or insufficient in its substance—let alone *on its face*. While the Court allowed the original claims to proceed to the extent that they "are based on alleged false statements about whether Splenda contains S6A," Dkt. 35 at 7, the Court previously dismissed a limited portion of Heartland's claims to the extent that they were based on the "falsity of Dr. Schiffman's statements about her research conclusion that S6A is dangerous, genotoxic, causes inflammation, and has other negative health effects." Dkt. 35 at 1. The crux of the Court's decision was that Heartland made "no allegations tending to support a plausible inference that Dr. Schiffman's research was based on *fraudulent data* or otherwise that her conclusions were a *result of quackery*." *Id.* at 2 (emphasis added). But this was before discovery—when the evidence of fraud and quackery was exclusively in the possession of Schiffman, her co-authors, and contract labs. Heartland now has more than sufficient allegations to meet this standard. The Amended Complaint adds numerous allegations to substantiate that Schiffman's statements that (1) Splenda contains S6A—and in dangerous amounts that supposedly exceed the "threshold of toxicological concern"; (2) S6A is "genotoxic"; and (3) her May 2023 Article conclusively established or found adverse health effects of S6A were the direct result of

fraudulent data, intentional misrepresentations, manipulated methodology, and shocking omissions—in other words, quackery. Ex. B at ¶107.

A. Schiffman's Fraudulent Data, Intentional Misrepresentations, and Unsupported Conclusions

Scientific conclusions may be protected speech only to the extent they are drawn from "*non-fraudulent data*, based on *accurate descriptions of the data and methodology* underlying those conclusions, on subjects about which there is legitimate ongoing scientific disagreement." *ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490, 498 (2d Cir. 2013) (emphasis added). Under this standard, courts have denied motions to dismiss where allegations showed that the statements at issue "falsely claimed that [certain weight loss] methods have been '*proven* effective'" and that the statements relied "on research that does not meet threshold standards for reliability." *Weight Watchers Int'l, Inc. v. Noom, Inc.*, 403 F. Supp. 3d 361, 377 (S.D.N.Y. 2019) (emphasis added). That is the case here.

The Amended Complaint lays out in detail how Schiffman manipulated data to show that she made false and misleading assertions that S6A is genotoxic and that her May 2023 Article *established* S6A's adverse health effects.[2] *See, e.g.*, Ex. B at ¶¶57–106, 108(b). But her research came nowhere near establishing that S6A was genotoxic. *Id.* She performed two experiments, a MultiFlow assay and a micronucleus assay, to supposedly "establish" the genotoxicity of S6A. Both are plagued by misrepresentations and false data.

[2] The Amended Complaint also explains that no amount of misconduct would allow Schiffman to say that *sucralose*, not S6A, is genotoxic. Ex. B at ¶57–106.

The first experiment, the MultiFlow assay, is at most a preliminary screening test designed to be overinclusive to produce a high false positive rate. *Id.* at ¶59. A positive result on this screening assay means only that follow-on testing is warranted, not that the article being tested (here, S6A) is conclusively genotoxic. *Id.* But to even reach the positive result she claims, she manipulated the data to achieve the result she wanted. *Id.* at ¶¶67–76. First, while claiming to use standard concentrations, she actually used concentration levels so high that it would have resulted in almost *any* substance producing results as positive for genotoxicity. *Id.* at ¶¶74–75. Second, while she expressly claimed to use the proper data values for a MultiFlow assay, she did not. *Id.* at ¶67–74. Instead, she used made-up data values without any support in literature and led to the positive result she wanted. *Id.*; *cf. CrossFit, Inc. v. Nat'l Strength & Conditioning Ass'n*, 2016 WL 5118530, at *7 (S.D. Cal. Sept. 21, 2016) (stating that fabricated data is "not be shielded by the First Amendment by virtue of being presented in an academic journal"). If she had used the proper data values for a MultiFlow assay, as she claimed, the results would actually have shown that S6A *was not* genotoxic. Ex. B at ¶71. Third, as discussed in the following section, she had another laboratory perform this MultiFlow screening test using the standard conditions and methods, and the results showed S6A *was not* genotoxic. *Id.* at ¶61–65. Schiffman suppressed these inconvenient (for her) results. *Id.* at ¶61–65, 132.

The second experiment, the non-GLP micronucleus assay,[3] was also only a screening test. *Id.* ¶78 & n.8. The problems do not end there. Schiffman purposefully

[3] "GLP" stands for Good Laboratory Practice. Certain agencies, like the EPA, accept only data from GLP studies when considering potential regulation. Researchers can perform

concealed that the S6A solution tested was contaminated by the presence of precipitate. *Id.* at ¶79–88. Schiffman falsely reported that S6A was genotoxic even though she obtained only one statistically significant results from the micronucleus test, which occurred at the highest concentration tested (and included visible precipitate). *Id.* And Schiffman altered her own study protocol midstream to be able to report that S6A is genotoxic when experiments under the original protocol did not show the results she wanted. *Id.* at ¶87.

In addition to the false statement that S6A is genotoxic, Schiffman also claimed that sucralose and S6A cause "leaky gut." She conducted and reported on two experiments, the TEER and permeability study and the RNA-seq study, as the basis for her statement. *Id.* at ¶90–102. Once again, both of these tests are screening tests or hypothesis-generating tests (conducted on an artificial "gut-like" platform that bears little resemblance to an actual intestine), and they are not meant for deriving conclusions. *Id.* And once again, Schiffman tested outrageously high concentrations of sucralose and S6A. *Id.* at ¶98–100. Under even the lowest concentrations of sucralose and S6A that Schiffman claimed to show negative effects on the gut, a person would need to consumer ***hundreds*** (sucralose) and ***thousands*** (S6A) of sucralose-sweetened energy drinks in a day to achieve the concentrations she relied on. *Id.*

These misrepresentations and methodology manipulation were not unintentional. When Schiffman made these false statements, she knew her research amounted to only

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non-GLP studies, including when the results are not meant for regulatory submission, because they are often cheaper and require less documentation. The micronucleus assay can be performed as either GLP or non-GLP studies. Schiffman directed the contract laboratory to perform only the non-GLP micronucleus assay. *See* Ex. B at ¶ 78 n.8.

screening or preliminary research *at most*. *See, e.g.*, *id.* at ¶¶147–148. But more importantly, at numerous points, others told her about the issues with her data, her methods, and her results. *See, e.g.*, *id.* at ¶¶128–153. She not only ignored them but specifically crafted her research to achieve her agenda. *See id.*

B. Schiffman's Shocking Omissions

Not only did Schiffman manipulate the methodology of her experiments to obtain the results she wanted, she buried data that showed that S6A is *not* genotoxic. *Id.* at ¶62–66, 129–135. Indeed, after the contract lab Schiffman originally hired (and whose data she ultimately published) completed their MultiFlow assay, Schiffman approached a second lab to review the first lab's results and conduct its own MultiFlow test. *Id.* That second lab told Schiffman *repeatedly* that their testing indicated that S6A is ***not*** genotoxic. *Id.* at ¶131. Even though Schiffman had this second lab's test results for two years at the time of the May 2023 Article's publication, she decided against even mentioning its results. *Id.* at ¶133. And after the publication of her Article, this laboratory was *shocked* be her claims, stating, "I thought we determined it was NOT genotoxic!" *Id.* at ¶131. Noting further that Schiffman "clearly had a bias going into this - I had several conversations with her - and our data didn't fit with her agenda. . . . Pretty unfortunate that she took this route though." *Id.*

* * *

All told, Schiffman's statements were drawn from "fraudulent data, based on [in]accurate descriptions of the data and methodology underlying those conclusions." *ONY*, 720 F.3d at 498. Put plainly, she was not conducting science—she was rigging the process

to deliver a predetermined outcome. Her false and disparaging statements are entitled to no First Amendment protection. While allegations regarding whether "research is reliable" and "meet[s] threshold standards for reliability" and "proves" something is generally "not properly resolved on a Rule 12(b)(6) motion," *Weight Watchers*, 403 F. Supp. 3d at 377, it most certainly is not properly resolved in a motion for leave to amend, *see Earthkind*, 2020 WL 8771419, at *2.

CONCLUSION

For the foregoing reasons, the Court should grant Heartland's motion for leave to file the Amended Complaint.

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CERTIFICATE OF COMPLIANCE

Pursuant to Local Rule 7.3(d)(1), the undersigned certifies that the word count of this brief is 3,192 words. The word count was determined with the word count feature of Microsoft Word software.

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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing was served on all counsel of record for the parties on July 24, 2025, by the Court's ECF system.

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